

AUG 07 2009



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510(k) Summary

K091039

Submitter information:

Applicant: Kowa Company, Ltd.
4-14, Nihonbashi-honcho 3-Chome
Chuo-ku, Tokyo, 103-8433 Japan

Contact: Satohiko Takanashi, PE

Date summary prepared: Aug. 4, 2009

Device identification:

Device trade name: KOWA FM-600
Regulation Number: 21 CFR 886.1570
Product code: MYC
Classification name: Ophthalmoscope, Laser, Scanning
Regulatory Class: Class II

Identification of predicate devices:

Kowa Company believes that this device is substantially equivalent to:

Laser flare meter FM-500 manufactured by Kowa, 510(k)# K913852,
Laser flare cell meter FC-1000 manufactured by Kowa, 501(k)# K880920.

Device description:

KOWA FM-600, here after refer to as FM-600, is a noninvasive flare photometry device that is able to assess anterior protein level quantitatively.

FM-600 consists of three units, Measurement unit, Operating unit and Power supply unit. The measurement unit is contained optical system including Laser, photo receiver and CCD camera for observation. The operating unit is contained Observation monitor, Analyzer of detected photon intensity, printer for output and migratory mechanism of the units. The power supply unit is contained Power unit.

Intended use:

KOWA FM-600 is an instrument to measure the protein level contained in aqueous humor of the anterior chamber of human eye.

Technical characteristics:

Kowa FM-600 is a single-function device of laser flare measurement. Kowa FM-600 and the predicate devices have similar technological characteristics for flare measurement. The flare measurement volume in anterior chamber, measurement aperture and laser intensity at the patient eye are same characteristics of the predicate devices.

The light sources of FM-600 are used a laser source for flare measurement and LED light for illumination to observe the measurement area. The laser light source wavelength is almost same to the predicate device. The light source for illumination is different type of the predicate device. To evaluate safety, tests based on optical hazard standards, ISO15004-2: 2007, IEC60825-1: 2007, and IEC60601-1: 1988 and related amendments, are performed and it is confirmed in equivalent level of safety to the predicate devices.

According to ISO5725-1 and ISO5725-2, repeatability and reproducibility are evaluated, and are obtained 1.5% for repeatability and 4% for reproducibility in standard deviation. The results are shown in Table A1.

Relation of flare value and using Bovine albumin solution, BSA, is shown in Figure A1.

Precision:

The precision is defined by standard deviation of measurement value built in calibrator of FM-600. This calibrator has a reflection ability of 80 photon counts per millisecond. The precision of FM-600 is less than 5% at 80 photon counts per millisecond.

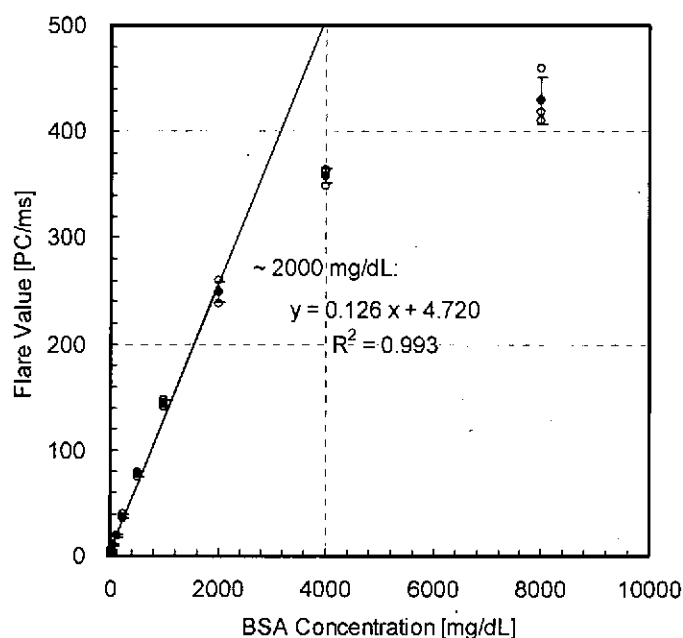


FIGURE A1. RELATION OF FLARE VALUE AND BSA CONCENTRATION

In figure, solid line is a linearity regression line calculated by the data up to 2000mg/dL in concentration. Briefly conversion factor is 100mg/dL equal to 13 photon count/millisecond. Error bar indicates standard deviation. The standard deviation is estimated measurements taken on the same albumin sample using different three instruments, including repeatability (in PC/ms). Measurement is performed 10 repeating at one concentration of BSA

TABLE A1. Repeatability and reproducibility (according to ISO 5725-1 and 5725-2) at eight different prepared BSA concentrations measured 30 times using three (3) instruments and ten (10) replicate measurements per instrument.

BSA concentration [mg/dL]	Mean flare values [PC/ms]	Repeatability* [PC/ms]	Reproducibility** [PC/ms]
2000	248.69	4.15	11.27
1000	144.28	2.57	4.00
500	77.49	1.51	2.73
250	37.52	1.09	2.19
125	18.97	0.80	1.07
62.5	10.30	0.53	0.94
31.3	5.03	0.29	0.65
15.6	2.93	0.56	0.53
0 (HBSS)	0.96	0.33	0.32

* Repeatability is an estimate of the standard deviation among measurements taken on the same albumin sample using the same instruments.

** Reproducibility is an estimate of the standard deviation among measurements taken on the same albumin sample using different instruments, including repeatability.

ISO5725-1: 1994 Accuracy (trueness and precision) of measurement methods and results - Part 1: General principles and definitions.

ISO5725-2: 1994 Accuracy (trueness and precision) of measurement methods and results - Part 2: Basic method for the determination of repeatability and reproducibility of a standard measurement method.

Substantial equivalency of performance

Comparison with the predicate device is shown in Table A2.

To evaluate performance equivalency, performance test using Bovine albumin solution as protein model in the anterior chamber is performed. From the studies of correlation and Bland-Altman plot of the flare value, KOWA FM-600 has good correlation and low valiance for the predicate device.

It is concluded that KOWA FM-600 is substantially equivalent to the predicate devices.

Table A2: Comparison with predicate devices			
	Proposed device	Predicate devices	
Proprietary name	KOWA FM-600	Laser Flare Meter FM-500	Laser Flare Cell Meter FC-1000
510(k) number	-	K91385	K880920
Indications for use or Scope	KOWA FM-600 is an instrument to measure the protein level contained in aqueous humor of the anterior chamber of human eye.	Quantitative measurement of protein concentration in the aqueous provides important information for evaluation anterior segment inflammation.	Quantitative measurement of protein concentration and cells in the aqueous provides important information for evaluation anterior segment inflammation.
Functions			
Slit lamp function	No	Yes	Yes
Cell measurement	No	No	Yes
Flare measurement	Yes		
Flare measurement function and principal parts			
Laser source	635nm Laser diode	670nm Laser diode	0.5mW 633nm Helium Neon Laser
Laser scanning width	0.6 mm		
Beam west diameter	20 μm		
Laser light intensity at the subject eye	Less than 0.05mW		
Photo detector	Photo multiplier tube		
Measurement area	0.3 x 0.5 mm ²		
Measurement time	0.5 second	0.5 second	1.0 second
Illumination light source	Infrared LED	12V, 30W Halogen lamp	6V, 30W Halogen lamp
Observation method	Electrical image by CCD camera	Binocular microscope	Binocular microscope
Fixation light source	Visible LED		



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-0609
Silver Spring, MD 20993-0002

KOWA Company, LTD.,
c/o Mr. Satohiko Takanashi
Chief Analyst
4-14, Nihonbashihoncho 3-chome
Chuo-ku, Tokyo
Japan 103-8433

AUG 07 2009

Re: K091039
Trade/Device Name: KOWA FM-600 Model LSS50
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: II
Product Code: MYC
Dated: July 7, 2009
Received: July 9, 2009

Dear Mr. Takanashi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Kesia Alexander for", is written over the typed name.

Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

510(k) Number (if know): K091039

Device Name: KOWA FM-600

Indications for Use:

KOWA FM-600 is an instrument to measure the protein level contained in aqueous humor of the anterior chamber of human eye.

Prescription Use ☒

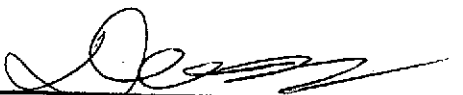
(Part 21 CFR 801 Subpart D) AND/OR

Over-The-Counter Use ☐

(21 CFR 801 Subpart C)

(PLEASE DO WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device


(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

8/7/2009

510(k) Number K091039